

Appl. No. : 10/700,355
Filed : November 3, 2003

REMARKS

The following remarks are responsive to the April 24, 2007 Final Office Action. Claims 11, 18, and 19 remain as previously presented, and Claims 12, 13, and 17 remain as originally filed. Thus, Claims 11-13 and 17-19 are presented for further consideration.

Response to Rejection of Claims 11-13 and 17-19 Under 35 U.S.C. § 103(a)

In the April 24, 2007 Final Office Action, the Examiner rejects Claims 11-13 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,063,108 issued to Salansky *et al.* ("Salansky"). Applicant respectfully traverses this rejection. In particular, Applicant submits that Claim 11 includes features which are not disclosed or suggested by Salansky.

Claim 11 as currently pending recites:

11. A method for accelerating the production of a vaccine by an in vitro cell culture, comprising:
providing an in vitro cell culture comprising cells useful in production of a vaccine; and
delivering an effective amount of electromagnetic energy to the in vitro cell culture, wherein delivering the effective amount of electromagnetic energy includes delivering electromagnetic energy having a power density of at least about 0.01 mW/cm² and a wavelength of about 780 nm to about 840 nm to the cells in the in vitro cell culture; wherein the delivering the electromagnetic energy results in the enhancement or improvement of the in vitro cell culture.

In the April 24, 2007 Final Office Action, the Examiner asserts that Salansky teaches a method for delivering an effective amount of electromagnetic energy with a wavelength of 800 nm to a cell culture (citing Salansky at column 8, lines 22-25) with a power density in the range of 0.2-10 mW/cm². However, Applicant submits that rather than disclosing the irradiation of a cell culture with light within the parameters recited by Claim 1, Salansky instead discloses irradiating biological tissue in a mammal with light having selected optical parameters. Applicant notes that all of the embodiments disclosed by Salansky are directed to *in vivo* irradiation for use as a medical treatment of a living mammal.

The only mentions of cell cultures provided by Salansky are made to highlight the differences between *in vitro* cell culture irradiation and *in vivo* living tissue irradiation. For example, at column 8, lines 22-27, Salansky discloses (emphasis added):

In cell culture experiments thin cell layers are usually uniformly exposed to light therefore intensity does not change significantly within the sample. For biotissue

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stimulation, the whole picture is different because light intensity (and dose) decreases with depth z.

In addition, Salansky explains at column 2, lines 38-41 that (emphasis added):

However, it is difficult to induce and observe these phenomena both in vivo and in vitro using the same optical parameters. Specific optical parameters are required to induce different photobiomodulation phenomena The range of optical parameters where “photobiomodulation” phenomena are observed may be quite narrow.

By highlighting the differences between *in vitro* and *in vivo* irradiation in this way, Salansky teaches away from applying the disclosed parameters for *in vivo* irradiation to the irradiation of *in vitro* cell cultures.

The Examiner cites Figure 1 of Salansky as supporting the assertion that “it would have been obvious for a person of ordinary skill in the art to recognize that the limitations to the treatment for *in vivo* therapy disclosed in Salansky et al. would have been used for *in vitro* cell culture, and therefore use the parameter in the method of Salansky et al. for *in vitro* cell culture with a reasonable expectation of success.” Applicant respectfully submits that Figure 1 of Salansky actually supports the opposite conclusion, i.e., that persons skilled in the art would not have an expectation of success in applying the *in vivo* irradiation parameters to *in vitro* cell culture irradiation. As disclosed by Figure 1 of Salansky, while *in vitro* cell culture data may be used in part for the development of appropriate *in vivo* treatment protocols, a considerable amount of experimentation and calculation using other information is required. Figure 1 of Salansky discloses that this development of clinical protocols includes using anecdotal data from human studies, data from animal studies, optical parameters regarding reflection, refraction, absorption, scattering, and remittance, and iterative modifications of the treatment protocols with pilot studies. Thus, Figure 1 of Salansky discloses that there is not a simple correlation between the parameters for the *in vivo* treatment protocols disclosed by Salansky and parameters for *in vitro* irradiation of cell cultures. Persons skilled in the art would therefore not expect to be able to merely apply the *in vivo* irradiation parameters to the *in vitro* irradiation of a cell culture.

For at least the above-stated reasons, Applicant submits that it would not be obvious to persons skilled in the art to apply the parameters for *in vivo* irradiation disclosed by Salansky to *in vitro* cell culture irradiation. Therefore, Applicants submit that Claim 11 is patentably distinguished over Salansky. Each of Claims 12, 13, and 17-19 depends either directly or indirectly from Claim 11, so each of these claims is also patentably distinguished over Salansky.

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Applicants respectfully request that the Examiner withdraw the rejection of Claims 11-13 and 17-19 and pass these claims to allowance.

Response to Rejection of Claims 11, 12, and 16 Under 35 U.S.C. § 103(a)

In the April 24, 2007 Final Office Action, the Examiner rejects Claims 11, 12, and 16 under 35 U.S.C. § 103(a) as being unpatentable over van Breugel et al., Lasers in Surgery and Medicine, 1992, Vol. 12, pages 528-537 (“van Breugel”). Applicant respectfully traverses this rejection. In particular, Applicant submits that Claim 11 includes features which are not disclosed or suggested by van Breugel.

While van Breugel discloses an *in vitro* photo-biomodulation study of human fibroblast cells, the Examiner acknowledges that van Breugel does not teach “a wavelength of about 780 nm to about 840 nm,” as recited by Claim 11. However, the Examiner asserts that the selection of a wavelength at about 780 nm to about 840 nm would have been a routine matter of optimization on the part of the artisan of ordinary skill, and that such artisans would recognize that modifying the wavelength in various ranges would be desired to obtain an optimal range of wavelengths for the method.

Figure 3 and the abstract of van Breugel disclose that in the particular study performed by van Breugel, the absorption spectrum of human fibroblast cells has a peak at 630 nm and helium-neon laser light having a wavelength of 632.8 nm was used to irradiate the *in vitro* human fibroblast cells. In addition, at page 535, first column, line 49 – second column, line 11, van Breugel discloses that (emphasis added):

A photobiological response entails the absorption of a specific wavelength of light by some unknown photoacceptor molecule. ... After absorbing a specific wavelength of light and generating its excited state, primary molecular processes within the acceptor molecule can lead to a measurable photoresponse, which determines the so called action spectrum. The complicated shape of the spectrum suggests that in human fibroblasts there are several molecules that serve as photoacceptors. In the visible light range absorption peaks were found around 420, 445, 470, 560, 630, 690, and 730 nm. At longer wavelengths a general decrease in absorption was observed.

Applicants submit that in view of the teachings of van Breugel, it would not be a routine matter for persons skilled in the art to utilize a wavelength “of about 780 nm to about 840 nm,” as recited by Claim 11. van Breugel teaches that it is important to utilize a specific wavelength at an absorption peak of the cells. van Breugel further teaches that human fibroblast cells do not have such absorption peaks in the wavelength range recited by Claim 11, and that absorption

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actually decreases in this wavelength range (see, Figure 3 of van Breugel). Therefore, persons skilled in the art would not expect that this wavelength range would produce any optimization of the photo-biomodulation study disclosed by van Breugel.

For at least the above-stated reasons, Applicant submits that utilizing a wavelength "of about 780 nm to about 840 nm," as recited by Claim 11, cannot be the result of mere routine optimization of the teaching of van Breugel. Therefore, Applicant submits that Claim 11 is patentably distinguished over van Breugel. Each of Claims 12 and 16 depends from Claim 11, so for at least the same reasons, these claims are also patentably distinguished over van Breugel. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 11, 12, and 16 and pass these claims to allowance.

Summary

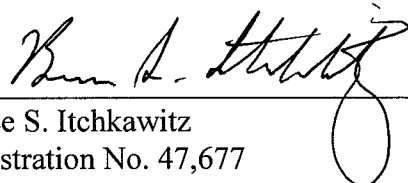
For at least the above-stated reasons, Applicant submits that Claims 11-13 and 17-19 are in condition for allowance, and Applicant respectfully requests such action.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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By: _____


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